Esaote, S.p.A.

JUN 2 5 2010

Special 510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR¶807.92(a).

807.92(a)(1)

Submitter Information

Esaote S.p.,A Via Siffredi 58 16153 Genova Italy

Contact Person:

Allison Scott

317.569.9500 x106

ascott@ansongroup.com

Date:

April 2, 2010

807.92(a)(2)

Trade Name:

6200 System

Common Name:

Ultrasound Imaging System

Classification Name(s):

Ultrasonic pulse Doppler imaging system 892.1550

Ultrasonic pulsed echo imaging system 892.1560

Classification Number:

90IYN; 90IYO

807.92(a)(3)

Predicate Device(s)

K051837, K060827, K081386

6100

Esaote, S.p.A.

Special 510(k) Summary 6200 System Esaote, S.p.A.

807.92 (a)(4)

Device Description

The 6100 is a mainframe ultrasound system, used to perform diagnostic general ultrasound studies. Its primary modes of operation are: B-Mode, M-Mode, XView, Multi View (MView), Trapezoidal View (TPView), Doppler, Color Flow Mapping, Amplitude Doppler (AD), Tissue Velocity Mapping (TVM) and Tissue Enhancement Imaging (TEI). The system is equipped with a LCD Color Display, a control panel and is capable of operating Linear, Convex, and Phased array probes.

The 6100 system has been cleared by FDA via K051837, K060827 and K081386.

The modified 6100, with respect to the cleared version 6100 via K051837, K060827 and K081386, is due to the improvements of the system. These modifications, that do not affect the intended use or alter the fundamental scientific technology of the device, are the following:

- a. New keyboard (control panel), where some control keys (knobs and keys) have been replaced by a touch screen.
- b. New plastic housing of the system both to include the touch screen and to give a new style
- c. New keyboard group PCBs lay out to interface the touch screen and to match the new organization of the panel keys.
- d. Software/Firmware modification to translate the touch screen information for the software: main software characteristics and performances have not been changed.

The 6200 is the model name of the modified 6100. The set of probes of the 6100 and the 6200 is exactly the same.

The 6200 system is manufactured under an ISO 9001:2000 and ISO 13485 certified quality system.

807.92(a)(5)

Intended Use(s)

Esaote's Model 6200 is a mainframe ultrasound system used to perform diagnostic general ultrasound studies including Cardiac, Transesophageal, Peripheral Vascular, Neonatal Cephalic, Adult Cephalic, Small organ, Musculoskeletal (Conventional and Superficial), Abdominal, Fetal, Transvaginal, Transrectal, Pediatric, Intraoperative (Abdominal), Laparoscopic and Other: Urologic. The 6200 system provides imaging for guidance of biopsy and imaging to assist in the placement of needles in vascular or other anatomical structures as well as peripheral nerve blocks in Musculoskeletal applications.

Esaote, S.p.A. 6200 Special 510(k) Page 42 of 1017

Special \$10(k) Summary 6200 System Esaote, S.p. V

The Virtual Navigator is a MyLab optional license that provides additional image information from a second modality like CT or MR, during a clinical ultrasound session. The second modality provides additional security in assessing the morphology of the ultrasound image.

Virtual Navigator can be used in the following application: Abdominal, Musculo-skeletal, Urologic, and Vascular.

The second modality image is not intended to be used as a standalone diagnostic image since it represents information of a patient that could not be congruent with the current (actual) patient position and shall therefore always been seen as an additional source of information.

The Virtual Navigator tracking system should not be used on or around persons with a cardiac pacemaker, and should not be used around life supporting equipment.

807.92(a)(6)

Technological Characteristics

The modifications reflected in this Special 510(k) for the 6200 are intended to improve the system's performance. The modifications have not altered the fundamental scientific technology or the intended use of the unmodified version of the 6100 cleared via K051837, K060827 and K081386.

DEPARTMENT OF HEALTH & HUMAN SERVICES





Food and Drug Administration 10903 New Hampshire Avenue Document Control Room –WO66-G609 Silver Spring, MD 20993-0002

'JUN 2 5 2010

EASOTE, S.P.A. % Ms. Allison Scott, RAC Regulatory Affairs Associate The Anson Group 11460 Meridian St., Ste 150 CARMEL IN 46032

Re: K100931

Trade/Device Name: 6200 Ultrasound Imaging System

Regulation Number: 21 CFR 892.1550

Regulation Name: Ultrasonic pulsed doppler imaging system

Regulatory Class: II

Product Code: IYN, IYO, and ITX

Dated: May 28, 2010 Received: June 1, 2010

Dear Ms. Scott:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the 6200 Ultrasound Imaging System, as described in your premarket notification:

Transducer Model Number

PA230	<u>C5-2 R13</u>
PA240	<u>CA123</u>
PA122	<u>CA430</u>
PA023	<u>CA431</u>
LA332	<u>CA541</u>
<u>LA435</u>	. <u>CA631</u>
LA522	<u>2CW</u>
LA523	<u>5CW</u>
LA923	<u>HF CW</u>

EC123	<u>IOE323</u>
EC1123	<u>LP323</u>
TRT33	<u>BC431</u>
TEE022	<u>BL433</u>
TEE132	<u>BE1123</u>

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Donald St. Pierre

Acting Director

Division of Radiological Devices Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and Radiological Health

Enclosure(s)

Model 6200 (Modified 6100)

In	ndications for Use
Special 510(k) Number (if know	vn):
Device Name:	6200 Ultrasound Systems
ultrasound studies including Car Adult Cephalic, Small organ, Mu Transvaginal, Transrectal, Ped Urologic. The 6200 system prov	inframe ultrasound system used to perform diagnostic general diagnostic general diagnostic general diagnostic general diagnostic, Transesophageal, Peripheral Vascular, Neonatal Cephalic usculoskeletal (Conventional and Superficial), Abdominal, Feta diatric, Intraoperative (Abdominal), Laparoscopic and Othe vides imaging for guidance of biopsy and imaging to assist in the lar or other anatomical structures as well as peripheral nervocations.
from a second modality like CT	ab optional license that provides additional image information or MR, during a clinical ultrasound session. The second curity in assessing the morphology of the ultrasound image.
Virtual Navigator can be used in Urologic, and Vascular.	the' following application: Abdominal, Musculo-skeletal,
represents information of a patien	ot intended to be used as a standalone diagnostic image since it ent that could not be congruent with the current (actual) patient ays been seen as an additional source of information.
	system should not be used on or around persons with a cardiac sed around life supporting equipment.
Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR Over-The-Counter Use (21 CFR 807 Subpart C)
(PLEASE DO NOT WRITE BEI NEEDED)	LOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
(Division Sign-Off) Division of Radiological Devices se of In Vitro Diagnostic Device Evaluation and Safe	of CDRH, Office of Device Evaluation (ODE)

1/1

6200 (modified 6100) Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode	Mode of Operations	_1			
Clinical Application	e e	×	DWD	cwD	Calor Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	Caff	Other (specify)
Ophthalmic											
Fetal	_	a	۵	4	۵	۵	-		Ь		5, 6, 7, 8, 9,
Abdominal	•	p.	e.	<u>.</u>	d	d	d		4		5, 6, 7, 8, 9, 12, 13, 15
Intraoperative (Abdominal)	۵	۵	a.		_	<u>.</u>	۵.		4		5, 6, 8, 9,
Intraoperative Neurological											
Pediatric	p.	۵.	_	p.	۱	d	a,		۵.		5.6.7.8.9.
Small Organ [1]	•	۵	a.	_	۵	p.	۵		d l		5, 6, 7, 8, 9,
Neonatal Cephalic	<u>a</u>	a	۵	۵.	4	۵.	n.		4		5, 6, 8, 9, 12
Adult Cephalic	_	a	-	a	a		۵.				5, 6, 8, 9, 12
Adult Cardiac	e.	-	_	۵.	<u>.</u>	_	a,	Δ.	a.	۵.	5, 6, 7, 8, 9, 10, 11, 12
Pediatric Cardiac	e,	۵	-	Ь	d	a	a.	۵	d		5, 6, 7, 8, 9, 10, 11, 12
Transesophageal (Cardiac)	a.	a.	<u>.</u>	۵	a.	а.	۵	۵	ď		5, 6, 8, 9, 10, 11, 12
Transcaophageal (Non Cardiac)											
Transrectal	۵	a.	a.	۵	۵.	۵	۵	٠	d		5, 6, 8, 9,
Transvaginal	Δ.		a.	a.	۵	۵	D.		Ь		5, 6, 8, 9, 12
Transurethral								•			
Intravascular											
Peripheral Vascular	_	a.	۵.	-	۵.	۵.	_		α.		5, 6, 8, 9,
Laparoscopic	_	a	n.	_	۵	n.	<u>a</u>		4		5, 6, 8, 9,
Musculo-skeletal Conventional [3]	<u>a</u> .	ρ.	۵	۵.	<u>-</u>	•	d		d.		5, 6, 8, 9, 12, 13, 14,
Musculo-skeletal Superficial [3]	a.	4	-	۵.	۵	۵	a.		<u>.</u>		5, 6, 8, 9, 12, 13, 14,
Other (Urological)	4	_		۵,	a.	۵.	ه.		d		5, 6, 8, 12,

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculo Skeletal - Nerve Block-

[4] Combined modes are: B+M+PW+CW+CFM+PD

|5| CMM |6| 3D |7| 4D |8| VPan |9| XView [10] Stress

(Division Sign-Off)

Division of Radiological Devices

Office of In Vitro Diagnostic Device Fraluation and Safety

510K

[11] Xstrain

[12] Compound Imaging (Mview) [13] TP-View [14] Elastography [15] Virtual Navigator

6100 Previously cleared via k051837, K060827 and k081386

Intended use. Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application B Ophthalmic P Fetal P	Σ									
almic	<u></u>	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTi	Other (specify)
	<u>.</u>	a	۵,	Ь	ď	а,		Δ.		5, 6, 8, 9, 12
Abdominal	a.	α,	a.	a.	۵.	a.		Д,		5, 6, 8, 9, 12 15
Intraoperative (Abdominal)										
Intraoperative Neurological										
Pediatric P	4	Ы	۵	d.	ď	4		d.		5, 6, 8, 9, 12
Small Organ [1] P	Ь	4	۵.	۵	d.	<u>n</u> .		d		5, 6, 8, 9, 12
Neonatal Cephalic								-		
Adult Cephalic P	۵.	ь,	۵	d.	Ъ	۵.		Ь		5, 6, 8, 9, 12
Adult Cardiac P	۵.	а.	۵,	<u>a</u> ,	Ω,	۵,	ď	d	С.	6, 8, 9, 10,
Pediatric Cardiac	α,	4	<u>a</u> .	d.	ď	<u>n</u> .	۵,	۵.		6, 8, 9, 10,
Transesophageal (Cardiac)	-									•
Transesophageal (Non Cardiac)										
Transrectal								-		
Transvaginal										
Transurethral										
Intravascular	_									
Peripheral Vascular	М	ч	Ь	d	Ь	Ъ		d		5, 6, 8, 9, 12
Laparoscopic										
Musculo-skeletal Conventional [3]							•			·
Musculo-skeletal Superficial [3]										
Other (Urological)										-

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] CMM

[6] 3D

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510K

[9] XView [10] Stress

[11] Xstrain

[12] Compound Imaging (Mview) [15] Virtual Navigator

Previously cleared via k091009

Intended use. Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Oliviani Anniination											
Cuncal Approacton	m	×	PWD	CWD	Color Doppler	Amplitude Doppler (PD)	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic										,	
Fetal	۵.	Δ.	۵.	c.	Ъ	ф	Ь		Ь		5, 6, 8, 9
Abdominal	۵	4	Δ.	a.	Ь	а	Ь		ď		5, 6, 8, 9
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	م	<u>a.</u>	<u>a</u>	Ы	Ч	, Ч	Ь		Ь		5, 6, 8, 9
Small Organ [1]	А	۵.	Ь	Ь	Ь	Ь	Ь		Ь		5, 6, 8, 9
Neonatal Cephalic											
Adult Cephalic	۵.	ď	Ь	n.	Ь	Ь	Ъ		Ъ		5, 6, 8, 9
Adult Cardiac	<u>a</u>	Д.	а.	<u>.</u>	Ъ	Ь	Ь	Ъ	Ь	Ъ	5, 6, 8, 9,
Pediatric Cardíac	ą.	Д.	Ъ	Ь	Р	Ь.	P	Ь	а		5, 6, 8, 9,
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)									•		
Transrectal									-		
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	Ь	Ь	Ь	Ь	ч	ሲ	۵.		Ъ		5, 6, 8, 9
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[4] Combined modes are: B+M+PW+CW+CFM+PD

[S] CMM

[6] 3D [9] XView

[10] Stress [11] Xstrain

Previously cleared via k091009

Office of In Vitro Diagnostic Device Eyaluation and Safety

510K

6200 (Modified 6100) - PA122 Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application B M PWD CWD Cold Ophthalmic Fetai P	CWD CC	Amplitude Combined	Color Velocity	Tissue Enhacement C	CnT1 Other
a a a a a a a a a a a a a a a a a a a	<u>a.</u>	Dopper 14	_	Imaging (TEI)	_
d d d d d d d d d d d d d d d d d d d	c			-	
d d d d d d d d d d d d	а.			-	
d d d d d d d d d d d d d d d d d d d	£	ů.		Ь	5, 6, 8, 9, 12
d d d d d d d d d	f				
d d d d d d d d d	,				
d d d d d d d d d	4	d.		P	5, 6, 8, 9, 12
d d d d d d d					
diac)	Ь	РР		Ъ	5, 6, 8, 9, 12
a. a. a. a.					
d d d	о. С.	<u>a.</u>	d.	ď	5, 6, 8, 9, 10,
a.			,		
a.	-				
a.					
a.					
d					
a.					
	۵.	а,		ď	5, 6, 8, 9, 12,
Laparoscopic					
Musculo-skeletal Conventional [3]					
Musculo-skeletal Superficial [3]					
Other (Urological)					

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[4] Combined modes are: B+M+PW+CW+CFM+PD

|5| CMM |6| 3D |9| XView

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Office of In Vitro Diagnostic Device Faluation and Safety

519K-I

[11] Xstrain [10] Stress

[15] Virtual Navigator

Previously cleared via k091009

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode	Mode of Operations	数日	,		
Clinical Application	В	×	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	Д,	Ь	d .	Ы	Ъ	Р	Ъ		Ь		5, 6, 8, 9, 12
Small Organ [1]				, ,							
Neonatal Cephalic	. ч	Ь	ď	Ъ	đ	Ъ	Ь		P		5, 6, 8, 9, 12
Adult Cephalic											
Cardiac [2]	α,	Ь	<u>а</u>	Ь	Δ.	а,	d	a,	Ь		5, 6, 8, 9, 10, 11, 12
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)								-	,		
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	Ь	Ь	ď	Ь	Ь	Ъ	ъ		Ь		5, 6, 8, 9, 12
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] CMM

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[10] Stress [6] 3D [9] XView

[11] Xstrain

Previously cleared via k091009

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

					•		Mode of Operations	ons			
Clinical Application	В	W.	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	٩	4	_		_	Δ.	۵.		d.		6, 8, 9, 12,
Abdominal	Ь	۵.	۵.		4	Ь	Ь		ď		6, 8, 9, 12,
Intraoperative (Abdominal)											
Intraoperative Neurological							,				
Pediatric	Ь	م	а		Ь	ď	۵.		đ.		6, 8, 9, 12,
Small Organ [1]	Ь	d.	ď		Ы	ď	٨		·		6, 8, 9, 12, 13, 14
Neonatal Cephalic	Ь	a,	ď		Ь	Ь	Д.		Ь		6, 8, 9, 12,
Adult Cephalic											
Cardiac [2]	ii ii	ម	ы		មា	Э	ы		B		6, 8, 9, 10,
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal					•						
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	Ь	Ь	d		Р	Ь	Ъ		Ь		6, 8, 9, 12,
Laparoscopic											
Musculo-skeletal Conventional [3]	۵	a.	ď		Ь	ď	ď		Δ,	•	6, 8, 9, 12, 13, 14
Musculo-skeletal Superficial [3]	c.	α.	a.		۵	Ы	e.		ι α		6, 8, 9, 12, 13, 14
Other (Urological)	ā	Ь	n.		Ь	a.	۵		<u>.</u>		6, 8, 9, 12,

N; New indication; P: Previosuly cleared by FDA; B:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD [6] 3D

[8] VPan [9] XView

[10] Stress

Office of In Vitro Diagnostic Device Evaluation and Safety

51 57 1

[11] Xstrain

|12| Compound Imaging |13| TP-View

[14] Elastography

Previously cleared via k091009

Intended use. Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinion Application											
	8	×	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI (i	Other (specify)
Ophthalmic	-										
Fetal	a.	d	ρ.		d.	ч	<u>а</u>		۵.	6,	6, 8, 9, 12,
Abdominal	Δ,	Ь	а.		Ь	ф	Ь		Р	, 6,	6, 8, 9, 12,
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	۵.	a.	a,		_	a.	a.		4	6,	6, 8, 9, 12,
Small Organ [1]	Δ.	a.	a.		۵.	a.	a.		a,	9	6, 8, 9, 12,
Neonatal Cephalic	Ь	a,	<u>a</u> .		4	d	а		a .	9	8, 9, 12,
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)					• • •						
Transesophageal (Non Cardiac)											
Transrectal				1							
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	۵.	۵.	Д.		a.	ď	e,		a.	νο̂	6, 8, 9, 12, 13, 15
Laparoscopic .											
Musculo-skeletal Conventional [3]	o,	Δ.	ā.		e.	ē.	۵		a.		6, 8, 9, 12, 13, 14, 15
Musculo-skeletal Superficial [3]	e,	۵.	d.		ь.	۵.	. d		ā.	1.6	6, 8, 9, 12, 13, 14, 15
Other (Urological)	Ь	Ь	Ь		Ъ	Ъ	Ь		ь	6,	6, 8, 9, 12,

N; New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculo Skeletal - Nerve Block-

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D

[8] VPan [9] XView

Division of Radiological Dévices Office of In Vitro Diagnostic Device Kvaluauon and Safery

510K

[12] Compound Imaging [13] TP-View

[14] Elastography [15] Virtual Navigator

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode	Mode of Operations	<u> </u>			
Clinical Application	B	Σ	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	۵.	a.	<u>.</u>		<u>_</u>	a.	a.		ч		6, 8, 9, 12,
Abdominal	a,	۵	a.		ď	Ь	Ь		. Р		6, 8, 9, 12,
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	ο.	۵.	Δ		a.	٩	<u>a</u>		d.		6, 8, 9, 12,
Small Organ [1]	ρ.	۵	d.		a.	Ь	ď		d		6, 8, 9, 12, 13, 14
Neonatal Cephalic	Д.	۵.	d.		۵	Ь	a .		Ъ		6, 8, 9, 12,
Adult Cephalic											
Cardiac [2]											,
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	d.	d	ď		Δ.	Δ.	ď		Ь		6, 8, 9, 12,
Laparoscopic											
Musculo-skeletal Conventional [3]	А	er.	<u>~</u>		Δ.	Δ.	a.		Ь		6, 8, 9, 12, 13, 14, 15
Musculo-skeletal Superficial [3]	d.	۵.	<u>a</u> .		d.	а	<u>a</u> ,		ч		6, 8, 9, 12, 13, 14, 15
Other (Urological)	Ы	c.	a.		а.	a.	a.		d		6, 8, 9, 12,

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD ae (9)

Division of Radiological Devices
Office of In Vitro Degnostic Device Evalyation and Safety

5 3 1

[9] XView [8] VPan

[12] Compound Imaging

[13] TP-View

[15] Virtual Navigator [14] Elastography

[15] Virtual Navigator

Previously cleared via k091009

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						W	Mode of Operations	Fito			
Clinical Application	B	×	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	Ъ	ч	۵		Ь	d .	۵		۵.		6, 8, 9, 12,
Abdominal	4	Ы	а.		Ь	Ь	ď		Ъ		6, 8, 9, 12,
Intraoperative (Abdominal)											
Intraoperative Neurological											-
Pediatric	Ь	d	۵		ū.	4	4		ď		6, 8, 9, 12,
Small Organ [1]	Ь	Ь	Ь		Ь	Ь	ď		ď		6, 8, 9, 12,
Neonatal Cephalic	д	а.	а		a.	۵.	Ы		d.		6, 8, 9, 12,
Adult Cephalic											
Cardiac [2]	ы	ā	ω	·	3	ы	Ð		6 2		6, 8, 9, 10,
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)									·		
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	ď	d	ď		Ь	ч.	d		ď		6, 8, 9, 12, 13, 15
Laparoscopic											
Musculo-skeletal Conventional (3)	d	۵	۵.		Ъ	Д	Δ.		a,		6, 8, 9, 12, 13, 14, 15
Musculo-skeletal Superficial [3]	<u>а</u>	a.	a.		Ь	ď	Δ.		а.		6, 8, 9, 12, 13, 14, 15
Other (Urological)	d.	-			Ь	ď	d		4		6, 8, 9, 12,

N: New indication; P. Previosuly cleared by FDA; E.Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D

(Division Sign-Off)
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Office of In Vitro Diagnostic Device Evaluation and Safety

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[10] Stress [8] VPan [9] XView

[12] Compound Imaging [11] Xstrain

[13] TP-Vicw

[14] Elastography

[15] Virtual Navigator

Previously cleared via k091009

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Application B iic P at (Abdominal) ative Neurological	- -	-	4000						֓֡֜֝֓֜֜֜֜֜֜֜֜֓֜֓֜֜֜֜֓֓֓֜֜֜֓֓֓֓֜֜֜֓֓֓֓֓֡֓֜֜֡֓֡֓֡֓֜֡֓֜	
nalmic P minal P pperative (Abdominal)		PWD	a ⊗	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnII	Other (specify)
minal P pperative (Abdominal)	-			:						
a. (<u> </u>	D.		<u>a</u> .	a.	а,		А		6, 8, 9, 12,
		۵		Δ.	d.	а,		۵		6, 8, 9, 12,
Pediatric P	п.	4	-	Ы	a.	ч		d		6, 8, 9, 12,
Small Organ [1] P P		<u>.</u>		Ы	4	ď		ď		6, 8, 9, 12,
Neonatal Cephalic P P	<u> </u>	ď		Ь	Ь	ч		а		6, 8, 9, 12,
Adult Cephalic										
Cardiac [2]	_	<u> </u>								
Transesophageal (Cardiac)										
Transesophageal (Non Cardiac)										
Transrectal		-								
Transvaginal										
Transurethral	ļ									
Intravascular									Ĺ.	
Peripheral Vascular P P	4	Ь		а.	Ь	n.		Ь		6, 8, 9, 12,
Laparoscopic										
Musculo-skeletal Convontional [3] P P		<u>a</u> .		a.	۵.	a.		α.		6, 8, 9, 12, 13
Musculo-skeletal Superficial [3] P P		Δ.		a.	۵.	D.		a.		6, 8, 9, 12, 13
Other (Urological) P P		а		a.	4	۵.		ፈ		6, 8, 9, 12,

N. New indication; P. Previosuly cleared by FDA; E.Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

GE [9]

[8] VPan

[9] XView

[12] Compound Imaging

[13] TP-View

(Division Sign-Off)
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Office of In Vitro Diagnostic Device Evaluation and Safety

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6200 (Modified 6100) - C5-2 R13

Intended use. Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application B M PW Ophthalmic P <td< th=""><th>PWD CWD</th><th></th><th></th><th></th><th></th><th></th><th></th><th></th></td<>	PWD CWD							
P		Color	Amplitude	Combined	Color.Velocity	Tissue Enhacement	CnTi	Other
ninal		Doppler	Doppler	[4]	Mapping (TVM)	Imaging (TEI)		(specify)
ninal P P P P P P P P P P P P P P P P P P P								
a. a. a. a.	d.	Ь	a.	Ы		d	37	5, 6, 8, 9, 12
a. a. a.	_	А	ď	Д		д.		5, 6, 8, 9, 12
a. a. a.								
a. a. a.						i		
a. a.	Ь	ч	Ь	۵,		Ь	-,	5, 6, 8, 9, 12
G.	Ь	ч	Ь	ъ		d	-	5, 6, 8, 9, 12
G.								
о. О.								
	a.	ď	d	Ъ		Ъ		5, 6, 8, 9, 10, 11, 12
Transrectal							,	
Transition								
Hansvagnian						,		
Transurethral								
Intravascular								
Peripheral Vascular P P P	Ь	P	Р	Ь		Ъ		5, 6, 8, 9, 12
Laparoscopic								
Musculo-skeletal Conventional [3] P P P	۵.	d	d.	o.		d.		5, 6, 8, 9, 12
Musculo-skeletal Superficial [3] P P P	a.	ч	a.	Ь		Ь		5, 6, 8, 9, 12
Other (Urological) P P	Ь	Ъ.	Ь	Ъ		Ь		5, 6, 8, 9, 12

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

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519

[5] CMM

as [9]

[9] XView [8] VPan

[10] Stress

[11] Xstrain [12] Compound Imaging

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application B M PWD CWD Color Amplitude Condre Volocity Tissue Enhacement CnIT Ophthalm: Ophthalm: P P P P P P P Fetal Madominal P P P P P P P Abdominal Instructoreactive (Madominal) P							Mod	Mode of Operations	500			
	Clinical Application	В	×	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
	Ophthalmic											
	Fetal	<u>a</u>	а	Δ,		۵,	a,	a.		۵.		5, 6, 8, 9, 12
	Abdominal	a.	ч	۵.		۵.	ď	<u>.</u>		۵.		5, 6, 8, 9, 12
	Intraoperative (Abdominal)											
	Intraoperative Neurological											
	Pediatric	D.	а	Ы		d.	а	d.		С.		5, 6, 8, 9, 12
	Small Organ [1]	n.	<u>a</u>	<u>.</u>		a,	ፈ	a.		Ъ		5, 6, 8, 9, 12
	Neonatal Cephalic	a.	a.	۵		а,	Ч	a,		Ь		5, 6, 8, 9, 12
a. a	Adult Cephalic											
	Cardiac [2]	۵	۵.	۵.		e.	a.	ā,		d.		5, 6, 8, 10,
	Transesophageal (Cardiac)											
	Transesophageal (Non Cardiac)											
a a a a a a a a a a a a a a a a a a a	Transrectal											
	Transvaginal											
d d d d d d d d d d d	Transurethral											
a a a a a a a a a a a a a a a a a a a	Intravascular											
d d d d d d	Peripheral Vascular	4	ď	4		Ы	Ы	Ь		Ь		5, 6, 8, 9, 12
a a a a a a a a a a a a a a a a a a a	Laparoscopic											
a. a. a.	Musculo-skeletai Conventional [3]	а.	o.	۵.		a.	d.	۵.		d.		5, 6, 8, 9, 12
Other (Urological)	Musculo-skeletal Superficial [3]	۵,	۵	۵.		Ъ	a.	α.		a.		5, 6, 8, 9, 12
	Other (Urological)											

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Sketetal - Nerve Block-

[4] Combined modes are: B+M+PW+CFM+PD

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation/and Safety

[5] CMM [6] 3D [8] VPan

510K

[9] XView

(10) Stress

|11| Xstrain

[12] Compound Imaging

Prescription Use Only Per 21 CFR 801 Part D Concurrence of CDRH, Office of In Vitro Diagnostics (OIVD)

Previously cleared via k091009

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mod	Mode of Operations	ons.			
Clinical Application	В	M	PWD	CWD	Color	Amplitude	Combined	Color Velocity	Tissue Enhacement	CuTI	Other
					Dappler	Doppler	[4]	Mapping (TVM)	Imaging (TEI)		(specify)
Ophthalmic											
Fetal	Ь	٩	Ъ		ч	ď	Ь		. Б		5, 6, 8, 9, 12
Abdominal	Ъ	e,	Δ,		д.	а,	۵.		d		6, 8, 9, 12,
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	P	ч	Ь		Ы	ď	ď		Δ.		5, 6, 8, 9, 12
Small Organ [1]	Ь	ď	ď		Ь	Ь	d		d		5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	۵.	а	۵		۵	ā	۵		ď		5, 6, 8, 9,
Transcsophageal (Cardiac)					:						
Transesophageal (Non Cardiac)									-		
Transrectal											
Transvaginal											
Transurethral							-				
Intravascular											
Peripheral Vascular	ď	d	ů,		a.	ō.	d		d		5, 6, 8, 9, 12, 15
Laparoscopic											
Musculo-skeletal Conventional [3]	۵.	a.	a.		е.	e.	Δ,		c.		5, 6, 8, 9, 12, 15
Musculo-skeletal Superficial [3]	a,	Δ.	<u>α</u>		D.	<u>a.</u>	D.		d.		5, 6, 8, 9, 12, 15
Other (Urological)	Ъ	Ъ	Ъ		Ъ	Ь	Ь		ų.		5, 6, 8, 9, 12, 15

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

| 4| Combined modes are: B+M+PW+CFM+PD | 5| CMM | 6| 3D | 8| VPan | 9| XView

Division of Radiological Devices / Office of In Vitro Diagnostic Device Evaluation and Safety

510K

[11] Xstrain [10] Stress

|12| Compound Imaging |15| Virtual Navigator

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mod	Mode of Operations	suc			
Clinical Application	В	×	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTl	Other (specify)
Ophthalmic											
Fetal	ы	а	Ь		a.	М	Ь		Ь		5, 6, 8, 9, 12
Abdominal	a,	۵.	۵.		٥.	ፈ	ď		. в		5, 6, 8, 9, 12,
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	đ.	4	۵.		Ь	d	Ь		д.		5, 6, 8, 9, 12
Small Organ [1]	e,	Ъ	a.		Ь	ь	Ъ		ď		5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	<u>a.</u>	ď	Ľ,		Ь	ď	А		ď		5, 6, 8, 9, 10, 1112
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											•
Transurethral											
Intravascular											
Peripheral Vascular	a.	Ь	Ъ		ď	a,	Д.		c.		5, 6, 8, 9, 12,
Laparoscopic											
Musculo-skeletal Conventional [3]	۵	ď	p.		۵.	ū,	۵.		a.		5, 6, 8, 9, 12, 15
Musculo-skeletal Superficial [3]	a.	d.	a.		<u>a.</u>	<u>a</u>	ď		Ь		5, 6, 8, 9, 12, 15
Other (Urological)	۵.	a.	Ь		۵	ь	Ъ		Р		5, 6, 8, 9, 12, 15

N. New indication; P. Previosuly cleared by FDA; E.Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeietal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

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Office of In Vitro Diagnostic Device Evaluation and Safety

[5] CMM

[6] 3D [8] VPan. [9] XView

510K

[10] Stress [11] Xstrain

[12] Compound Imaging

[15] Virtual Navigator

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application	B	M	PWD	CWD	Color	Amplitude	Combined	Color Velocity Manning (TVM)	Tissue Enhacement	CnTI	Other (specify)
					coppie	nobbici	E	(mar) Sunddam	fr 99	1	(Canada)
Ophthalmic											
Fetal	Z	N	Z		z	N	N		Z	LO.	5, 6, 8, 9, 12
Abdominal	z	z	z		z	N	z		z	Ś.	, 6, 8, 9, 12, 15.
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	z	z	z		z	z	z		N		5, 6, 8, 9, 12
Small Organ [1]	z	z	2,		N	Z	N		N	S	5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	z	z	z	-	z	Z	Z		z	เก	6, 8, 9, 10,
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)					-				-		
Transrectal											
Transvaginal											
Transurethral											
Intravascular									,		
Peripheral Vascular	z	ĸ	z		Z	Z	z		N	S	5, 6, 8, 9, 12, 15
Laparoscopic											
Musculo-skeletal Conventional [3]	z	z	z		Z	z	Z		Z	<u>ທີ່</u>	, 6, 8, 9, 12, 15
Musculo-skeletal Superficial [3]	z	z	z	_	z	z	Z		z		5, 6, 8, 9, 12, 15
Other (Urological)	z	z	z		z	z	z		Z	5	5, 6, 8, 9, 12, 15

N. New indication; P. Previosuly cleared by FDA; E.Added under Appendix E

.[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[5] CMM

and Safety

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[6] 3D

[8] VPan [9] XView

[10] Stress [11] Xstrain

[12] Compound Imaging [15] Virtual Navigator

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode	Mode of Operations	811			
Clinical Application	B	Σ	DWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal	d.	۵.	e.		a.	a.	۵.		d		5, 6, 8, 9, 12
Abdominal	d,	ď	d.		C.	۵.	۵.		Ą		5, 6, 8, 9, 12,
Intraoperative (Abdominal)		:									
Intraoperative Neurological											
Pediatric	а.	Ь	۵		Ь	Ь	Ы		Ь		5, 6, 8, 9, 12
Small Organ [1]	۵	Ч	Ь		Ь	Ъ	Ъ		ď		5, 6, 8, 9, 12
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]	ď	d	ч		Ъ	Ь	ů,		P.		5, 6, 8, 9, 10,
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
E Caronina Contraction											
Hansteria											
Transvaginal									,		
Transurethral											
Intravascular											
Peripheral Vascular	d	d	а		ď	Ь	ч.		<u>C</u> .		5, 6, 8, 9, 12, 15
Laparoscopic											
Musculo-skeletal Conventional [3]	d	٠.	۵.		d	d.	d		ď		5, 6, 8, 9, 12, 15
Musculo-skeletal Superficial [3]	ρ.,	a.	д.		۵.	d.			ů.		5, 6, 8, 9, 12, 15
Other (Urological)	Ь	Ω,	_		a.	d	d.		ď		5, 6, 8, 9, 12, 15

N. New indication; P. Previosuly cleared by FDA; E.Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:
B+M+PW+CFM+PD
[5] CMM
[6] 3D

(Division Sign-Off)
Division of Radiological Devices
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[8] VPan [9] XView

[10] Stress

[11] Xstrain [12] Compound Imaging

[15] Virtual Navigator

Intended use. Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode	Mode of Operations	13			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal						-					
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											•
Adult Cephalic										,	
Cardíac [2]				۵							
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral			•								
Intravascular						•					
Peripheral Vascular				Ь							
Laparoscopic										,	
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]								,			
Other (Urological)						,					

N. New indication; P. Previosuly cleared by FDA; E.Added under Appendix E

[2] Cardiac is Adult and Pediatric

[4] Combined modes are: CW

510K

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Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode	Mode of Operations	138			
Clinical Application	В	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic					i						:
Fetal											,
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)								-			
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular				Ь							
Laparoscopic			Ĺ								
Musculo-skeletal Conventional [3]									•		
Musculo-skeletal Superficial [3]						,	,				
Other (Urological)											

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Office of In Vitro Diagnostic Device Evaluation and Safety N: New indication; P: Previosuly cleared by FDA; E:Added unge

[4] Combined modes are: CW

Previously cleared via k091009

5 1 1

6200 (Modified 6100) - HF CW

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode	Mode of Operations	ns			
Clinical Application	В	W	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic											
Fetal											
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic					•				·		
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											!
Transesophageal (Non Cardiac)	·		<u> </u>								
Transrectal						ļ					
Transvaginal											
Transurethral								:			į
Intravascular											
Peripheral Vascular				z							
Laparoscopic						į					
Musculo-skeletal Conventional [3]				_	-						,
Musculo-skeletal Superficial [3]		<u> </u>	<u> </u>	1							
Other (Urological)											
					1	17 W 20	2. B	1/5			

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

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Office of in Vitro Diagnostic Device Evaluation and Safety

[4] Combined modes are: CW

To be cleared via this submission

Intended use. Diagnostic ultrasound imaging or fluid flow analysis of human body as follows.

						777	Wilder of Contraction	e iii			
Clinical Application	В	M	PWD	CWD	Color Dappler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTi	Ot her (specify)
Onhthalmic											
Fetal	a.	Ч	Ь		4	Ь	Ч		Ь		6, 8, 9, 12
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)							_	_			
									p		68912
Transrectal	<u>а</u>	d	۵		Ь	Ь	n.,				21 6 6 6
Transvaginal	d.	Ы	d.		Ь	а	۵		<u>.</u>		0, 0, 9, 12
Transurethral											
Intravascular					:						
Peripheral Vascular			:								
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]			_	_							
Other (Urological)	d.	a.	Δ.	۵	۵.	D.	۰.		۵.		6, 8, 9, 12,

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[4] Combined modes are: B+M+PW+CFM+PD

[5] CMM

as [9]

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51 1

[9] XView

[8] VPan

[12] Compound Imaging

[15] Virtual Navigator

Previously cleared via k091009

Intended use. Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						TOTAL STREET	Mode of Operations				
Clinical Application	В	×	DWD	CWD	Color	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
					roppin.	3400					
Ophthalmic						í			۵		5.6.8.9.12
Fetal	Ь	Ь	۵		۵	Δ.	7		-		
Abdominal						ļ					
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric					:						
Small Organ [1]							191. 003				
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
						1	,		0		5.6.8.9.
Transrectal	G.	<u>n</u>	<u>a.</u>		М		ъ.				12, 14
Transvaginal	4	Ь	Ь	!	Ь	Ь	Ь		a,		5, 6, 8, 9, 12
Transurethral								•			
Intravascular									-		
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial (3)						-					
Other (Urological)	Ь	d.	a.	Ь	<u>a.</u>	а	Ы		P		5, 6, 8, 9, 12

N: New indication; P: Previosuly cleared by FDA; E.Added under Appendix E

[4] Combined modes are: B+M+PW+CFM+PD

[5] CMM

[6] 3D

[9] XView (8) VPan

[12] Compound Imaging

[14] Elastography

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6200 (Modified 6100) - TRT33

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode	Mode of Operations	Su			
					,					Ē	Othor
Clinical Application	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Ennacement Imaging (TEI)		(specify)
Ophthalmic											
Fetal	ធ	a	घ		3	3	E		33		0, 0, 9, 14,
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic							ŀ				
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
			,		c	c	٥		d		6, 8, 9, 12,
Transrectal	ы.	Δ,	à.	,	٠.	١.,	_		;		13, 14
Transvaginal	d	<u>.</u>	α,		ď	d.	۵.		<u>-</u>		0, 0, 9, 12,
Transurethral					-			-			-
Intravascular											
Peripheral Vascular											
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)	d	Д	Ь		Ь	А	Ь		Ь		6, 8, 9, 12,
					,			-			

N: New indication; P: Previosuly cleared by FDA; E.Added under Appendix E

[4] Combined modes are:B+M+PW+CFM+PD

[5] CMM

(6) 3D (8) VPan

[9] XView

[12] Compound Imaging

[13] TP-View

[14] Elastography

Previously cleared via k091009

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6200 (Modified 6100) - TEE022 Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application B M PWD CWD Color Amplitude Combined Color Petal Abdominal	Mode of Operations
PWD Color Amplitude Combined PWD Color Color PWD	
Initial	Combined Color Velocity Issue Entracement [4] Mapping (TVM) Imaging (TEI)
Departive (Abdominal)	
ive (Abdominal) ive Neurological in [1] cphalic cphalic alic lageal (Cardiac)	
ive (Abdominal) ive Neurological ive Neurological in [1] cphalic chalic lalic	
li (Cardiac) l (Cardiac) l (Non Cardiac) l (Non Cardiac) lular al Conventional [3]	
lic I (Cardiac)	
diac) P P P P P P P P P P P P P P P P P P P	
diac) p p p p p p p p p in p p p p p p p p p p	
diac) p P P P P diac)	
diac) Diacy Di	
Transesophageal (Non Cardiac) Transrectal Transvaginal Transurethral Intravascular Peripheral Vascular Peripheral Vascular Beripheral Vascular Laparoscopic Musculo-skeletal Conventional [3]	d d
Transvectal Transvaginal Transurethral Intravascular Peripheral Vascular Eaparoscopic Musculo-skeletal Conventional [3] Musculo-skeletal Conventional [3]	
Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional [3]	
Transvaginal Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional [3]	
Transurethral Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional [3]	
Intravascular Peripheral Vascular Laparoscopic Musculo-skeletal Conventional [3]	
Peripheral Vascular Laparoscopic Musculo-skeletal Conventional [3]	
Laparoscopic Musculo-skeletal Conventional [3]	
Musculo-skeletal Conventional [3]	
Musculo-skeletal Superficial [3]	-
Other (Urological)	

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[4] Combined modes are: B+M+PW+CW+CFM+PD

[S] CMM

[6] 3D [9] XView

[10] Stress [11] Xstrain

Previously cleared via k091009

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6200 (Modified 6100) - TEE132

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode	Mode of Operations	118			
Clinical Application	В	W	PWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic								,			
Fetal											E
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological								-			
Pediatric							•				:
Small Organ [1]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac [2]											9
Transesophageal (Cardiac)	<u>a</u> ,	۵	Ь	ч	Ъ	G.	ď	ď	a.		5, 6, 9, 10,
Transesophageal (Non Cardiac)											
Transrectal	<u> </u>								.		
Transvaginal								i,			
Transurethral											
Intravascular											
Peripheral Vascular	<u>.</u>									_	
Laparoscopic											
Musculo-skeletal Conventional [3]											
Musculo-skeletal Superficial [3]											
Other (Urological)											·
								İ			

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[4] Combined modes are: B+M+PW+CW+CFM+PD

[5] CMM [6] 3D [9] XView

[10] Stress

510X

[11] Xstrain

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6200 (Modified 6100) - IOE323

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode	Mode of Operations	\$ C			
Clinical Application	m	×	PWD	cwb	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTi	Other (specify)
Ophthalmic											
100	۵.	а	а		Ь	α.	d		Δ.		6, 8, 9, 12,
Abdominal	۵.	۵.	۵.		Ь	ā,	Ь		Ы		6, 8, 9, 12,
Intraoperative (Abdominal)	4	Ь	д.		Ь	а	Ь		d		6, 8, 9, 12,
Intraoperative Neurological								_			
Pediatric	Ь	e.	<u>_</u>		a,	d	d		Д		6, 8, 9, 12,
Small Organ [1]	۵,	<u>a</u>	Ы		a.	e.	Ь		ρ,		6, 8, 9, 12, 13, 14
Neonatal Cephalic	a	۵	۵.		Ь	ч	Ь		G.		6, 8, 9, 12,
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											ļ
Transrectal											
Transvaginal											
Transurethral			,								
Intravascular									1		. 0
Peripheral Vascular	Δ,	Ь	۵.		Ь	ů.	۵.		۲.		0, 0, 9, 12,
Laparoscopic									ļ		9
Musculo-skeletal Conventional [3]	۵.	<u>a</u>	<u>a</u>		۵.	۵.	ď		Δ.		0, 6, 9, 12,
Musculo-skeletal Superficial [3]	۵.	a.	۵.		<u>a.</u>	ď	Ь		d .		6, 8, 9, 12, 13
Other (Prological)	۵.	_	۵.		a.	Ь	d		Ь		6, 8, 9, 12,

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[8] VPan [6] 3D

[9] XView

[12] Compound Imaging

[13] TP-View

[14] Elastography

Previously cleared via k091009

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Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety 510K

Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode	Mode of Operations	su			
Clinical Application	В	M	PWD	CWD	Color	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Opnima	,	,	,		o	۵	Д		Ы		5, 6, 8, 12,
Fetal	Ь	۵			L,		. 6		d		5, 6, 8, 12,
Abdominal	d	a.	а.		Ь	۵.	7-		•		
Intraoperative (Abdominal)											
Intraoperative Neurological		i									5 6 8 12
Pediatric	ď	d.	Ь		O.	<u>م</u>	ů,		_ F		5 6 8 19
Small Organ [1]	Ы	Р.	а		е.	<u>6.</u> ,	α,				6 6 6
Neonatal Cephalic								į			
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
(Non Cardiac)									L	_	
Hallsesophiagear (1011 Careac)											
Transrectal					:			,			
Transvaginal											
Transurethral											
Intravascular											9
Peripheral Vascular	Ы	۵.	<u>.</u>		Ь	Ь	д.		a.		5, 0, 6, 12,
Lanaroscopic	<u>a.</u>	а.	а.		۵.	Ъ	۵.		a.		3, 0, 0, 12,
Musculo-skeletal Conventional [3]			-					_			
Musculo-skeletal Superficial [3]											
Other (Urological)											

. N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[4] Combined modes are: B+M+PW+CW+CFM+PD

[6] 3D [8] VPan [9] XView

[12] Compound Imaging [13] TP-View

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Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

Clinical Application B M PWD Ophthalmic P P P Fetal P P P Abdominal Intraoperative (Abdominal) P P P Intraoperative (Abdominal) P P P Intraoperative (Abdominal) P P P Pediatric P P P Small Organ (1) E E E Neonatal Cephalic P P P Adult Cephalic P P P Transesophageal (Cardiac) P P P Transesophageal (Non Cardiac) P P P	Q _M O	Color Doppler P P P P P P P P P P P P P P P P P P P	Doppler P	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
minal) logical logical PPP PP PP reduce PPP PP	 - - - - - - - - 			4	Mapping (TVM)	Imaging (TEI)		(specify)
ve (Abdominal) ve Neurological p P P re (Abdominal) ve Neurological p P P re (B)		a. a. a. a.	0. 0.					
ve (Abdominal) ve Neurological ve Neurological p		a a a	a a					
ninal		L 0. W		4		a.		5, 6, 7, 8, 9,
d		a. a. w	۵ ،	-				56789
diac]	0.00	a 63		۵				5
ative Neurological P P P San [1] E E E Cephalic P P P Dhalic P P P 2] P phageal (Cardiac) P P phageal (Non Cardiac)	0. 01	а. ы	ĺ					
gan [1] £ £ Cephalic P P Dalic P P 2] P P phageal (Cardiac) phageal (Non Cardiac) P	7. 63	ட ம				,		26789
gan (1) E E Cephalic P P Dalic P P 2 P P phageal (Cardiac) P P	61	ы	c.	Ъ				
Cardiac)		1	ធ	Œ		13		5, 6, 8, 9, 12
P P P P P P P P P P P P P P P P P P P								
ageal (Cardiac)	֡							56789
Transesophageal (Cardiac) Transesophageal (Non Cardiac)	d.	d	Δ.	Δ,				10, 11, 12
Transesophageal (Non Cardiac)								
		-						
Transrectal								
Transvaginal								
Transurethral								
Intravascular			İ					2.6.8.9.12
Peripheral Vascular P P P	Ь	۵.	۵.	Δ.		.		
Laparoscopic						5		010883
Musculo-skeletal Conventional [3] P P P	а.	ρ.	а.	<u>а</u> ,		L		1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1
Musculo-skeletal Superficial [3] P P P	<u>-</u>	d	Œ.	ē.		à. 	_	3, 0, 6, 9, 12
Other (Urological) P P P		<u>-</u>	Ω.,	۵.		d		6, 6, 3, 9, 12

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Musculo Skeletal - Nerve Block

[4] Combined modes are:
B+M+PW+CFM+PD
[5] CMM
[6] 3D
[7] 4D

[10] Stress

[11] Xstrain [12] Compound Imaging

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Intended use: Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

						Mode	Mode of Operations				
Clinical Application	m	×	DWD	CWD	Color Doppler	Amplitude Doppler	Combined [4]	Color Velocity Mapping (TVM)	Tissue Enhacement Imaging (TEI)	CnTI	Other (specify)
Ophthalmic					-						
Fetal	Д	Ь	d.		d.	ρ.	۵		ď		6, 7, 8, 9, 12, 13
Abdominal	d.	a.	a.		Ь	ď	P		۰	Ů	6, 7, 8, 9, 12, 13
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric	а	Ы	۵		d	ď	Р		د .		6, 7, 8, 9, 12,
Small Organ [1]	a.	ď	a.		ď.	Ь	d		e.	_	6, 7, 8, 9, 12, 13
Neonatal Cephalic	d	ď	<u>a</u>		d.	Ь	Ь		Δ.		6, 8, 9, 12,
Adult Cephalic											
Cardiac [2]											
Transcsophageal (Cardiac)				·							
Transesophageal (Non Cardiac)											
Transrectal											
Transvaginal											
Transurethral											
Intravascular											
Peripheral Vascular	Ь	ч	Ь		ů.	ď	ρ.,		ď		6, 8, 9, 12,
Laparoscopic											
Musculo-skeletal Conventional [3]	d.	۵.	e,		d	ρ.	<u>а</u>		£.		6, 8, 9, 12, 13
Musculo-skeletal Superficial [3]	a. -	a.	<u>a</u>		a.	Ь	а,		۵		6, 8, 9, 12, 13
Other (Urological)	4	٩.	a.		<u>а</u> ,	d	а,		d		6, 8, 9, 12,

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[1] Small Organs includes Breast, Thyroid and Testicles

[2] Cardiac is Adult and Pediatric

[3] Muscuto Skeletal - Nerve Block

[4] Combined modes are: B+M+PW+CFM+PD

[6] 3D

[9] XView [7] 4D

[12] Compound Imaging [13] TP-View

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Office of in Vitro Diagnostic Device Evaluation and Safety

6200 (Modified 6100) - BE1123

Intended use. Diagnostic ultrasound imaging or fluid flow analysis of human body as follows:

		l				Mod	Mode of Operations	suc			
	c	2	Citize	GW.	20100	Amplifitade	Combined	Color Velocity	Tissue Enhacement	CrITI	Other
Clinical Application	n	ivi	rw U)	Doppler	Doppler	[4]	Mapping (TVM)	Imaging (TEI)		(specify)
Ophthalmic											
Fetal	Ъ	d	Ь		d	d	Ь		ď		5, 6, 7, 9, 12
Abdominal											
Intraoperative (Abdominal)											
Intraoperative Neurological											
Pediatric											Į
Small Organ [1]									-		
Neonatal Cephalic								,			
Adult Cephalic											
Cardiac [2]											
Transesophageal (Cardiac)											
Transesophageal (Non Cardiac)											
		·									4
Transrectal	а.	d.	ፈ		d.	Ь	Ь	,	ч.	,	5, 6, 8, 9, 12
Transvaginal	Ь	<u>a</u>	<u>a.</u>		Ь	Ь	Ь		Р		5, 6, 8, 9, 12
Transurethral											
Intravascular											
Peripheral Vascular									-		
Laparoscopic		1								· [
Musculo-skeletal Conventional [3]	-										
Musculo-skeletal Superficial [3]											
Other (Urological)	Ь	а	Ь		Ы	Ь	Ь		ь р		5, 6, 9, 12

N: New indication; P: Previosuly cleared by FDA; E:Added under Appendix E

[4] Combined modes are: B+M+PW+CFM+PD

B+M+PW+CFM+PD [5] CMM

[6] 3D

[9] XView

[12] Compound Imaging

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